MINUTES FROM THE EPA/SCIENCE ADVISORY BOARD
Drinking Water Committee Meeting
March 13-14, 2000

PURPOSE: The Drinking Water Committee (DWC) met in Washington, DC on March 13-14, 2000 to review the Environmental Protection Agency's (EPA) draft proposed rules on: 1) long-term 1 enhanced surface water treatment and 2) ground water. The Committee also received briefings on EPA's activities on: 1) arsenic, 2) non-radon radionuclides, 4) the Candidate Contaminant List Research Strategy, and 3) Microbial/ Disinfection Byproduct Stage 2 decision making. The meeting was announced in the Federal Register at FR Vol. 65, No. 39, Page 10493 (February 28, 2000) (see Attachment A). An agenda is included as Attachment B.

LOCATION: The meeting was held in the US EPA Science Advisory Board Conference Room, Room 6013, Ariel Rios North Building, 1200 Pennsylvania Ave., NW, Washington, DC.

PARTICIPANTS: The following SAB members, consultants, and staff participated in this meeting of the DWC: Drs. Bull, Baker, Davis, De Leon, Dragan, Evans, Harper, Moe, McMullen, O'Melia, Toranzos, and Trussell. A committee roster is included as Attachment C. EPA Staff included Mr. Thomas Miller, Designated Federal Officer and Ms. Dorothy Clark, Management Assistant. Persons from the Agency and public who attended the meeting are indicated on the sign-in sheets (Attachment D).

MEETING SUMMARY: A summary of the committee's activities follows.

A. Monday, March 13, 2000

1. Opening Remarks

9:00 - 9:15 am **Welcome and Introductory Remarks**
Dr. Richard Bull, Chairman

Dr. Bull welcomed persons from the Committee, EPA, and the public. In the interest of full public disclosure, the DWC members noted for the record their names and affiliation. They also mentioned their past involvement with issues related to those to be discussed at the meeting, and any EPA funding they receive in support their research. No member involved in the meeting had a legal Conflict of Interest relative to any of the agenda items.

2. Opening Remarks by the Agency

9:15 - 9:30 am Mr. James Taft, US EPA Office of Ground Water and Drinking Water

Mr. Taft presented an overview of the drinking water regulatory activities that have been pursued since the February 1999 DWC meeting and introduced the items for the day's discussion, the statutory requirement for SAB interaction on proposed rules [Safe Drinking Water Act (SDWA) Section 1412 (e)], and the time lines associated with the items on the agenda. Mr. Taft noted that the rule proposals to be discussed are still undergoing Office of Management and Budget review and that that review could present the possibility of changes in

the proposals prior to publication.

Dr. Bull noted the importance of timing in the DWC reviews and response to EPA. He noted the importance of the day's presentations to allowing the DWC to plan for effective reviews of items that are to be coming to the Committee for review later in the Fiscal Year (arsenic, microbial/disinfection byproduct stage 2 issues, etc.).

3. Long-Term 1 Surface Water Treatment/Filter Backwash Rule Proposal

9:30 - 9:50 am Mr. Jeff Robichaud, OGWDW

Mr. Robichaud presented a brief introduction to the structure, content and status of the draft proposed Long-term 1 Surface Water Treatment/Filter Backwash Rule (See Attachment E_1, E_2, and E_3). SDWA 1996 requires a final Federal Register publication of the rule by November 2000 and regulations that govern the recycling of filter backwash within the treatment process of a public water system by August 2000 unless such recycling has been addressed by the Administrator's ESWTR prior to such date. Health concerns focus on *Cryptosporidium*, from human and animal waste, which is not inactivated by standard disinfection practices.

LT1 Regulatory Provisions address: 1) combined filter effluent turbidity, 2) individual filter turbidity monitoring, 3) a disinfection bench-marking process, 4) 2-log *Cryptosporidium* removal, 5) inclusion of *Cryptosporidium*, in the definition of ground water under the direct influence (GWUDI) of surface water, 6) inclusion of *Cryptosporidium* into existing watershed requirements, and a 7) requirement that all newly constructed reservoirs be covered.

Filter Backwash Regulatory Provisions state that: 1) recycle is to be returned prior to the point of primary coagulant addition, 2) systems that recycle without equalization or treatment are required to gather recycle data and submit a report to State officials, and 3) systems which practice direct filtration are required to report their recycle treatment capability to State officials.

9:50 - 10:00 am **Break**

10:00 - 10:05 am **Public Comment**:

a) American Water Works Association: Dr. Alan Roberson, Director of Regulatory Affairs, American Water Works Association, provided a comment for consideration of the DWC members (see Attachment F). He noted that the emergency Federal Register notice provided a short turnaround for his association to prepare for the meeting and requested additional time to submit written comments. The FR notice provides that additional time noting that written comments can be submitted up until 15 days after the meeting (March 29, 2000).

Dr. Roberson stated that the provisions of the rule are atypical and obscure costs associated with the rule; that there are inadequate data on the relationship between recycling practices and finished water quality and a lack of linkage between the requirements and defined health benefits, there is a need for additional research, and the importance of substantial SAB review to proposed rules.

10:05 - 11:00 am DWC and EPA representatives:

The members discussed the technical background of the rule making with EPA

representatives. Because no specific charge was provided to the DWC for this rule the generic SDWA 1412(e) "request for comments requirement" provided the focus for the discussion. The Lead Discussant was Dr. Trussell. Associates Discussants were Drs. McMullen and O'Melia. Issues discussed included: 1) how one decides whether plants are conventional or direct filtration; softening plants and winter turbidity levels; appropriate recycling points; covering requirement for only new reservoirs; the ability of small systems to meet the 0.3 NTU requirement; performance vs. capacity requirements; high flow periods and their correlation with water quality; number of filters in specific plants; and the role of training in meeting requirements. The DWC members decided to provide written comments to the Agency (See discussion below in these minutes on Tuesday, 3/14/2000, from 8:00 am until 10:00 am).

4. Ground Water Rule Proposal

11:00 - 11:20 am Mr. Eric Burneson, OGWDW,

Mr. Burneson presented a brief introduction to the to the structure, content and status of the draft Ground Water rule (See Attachment G_1, G_2, G_3, G_4, and G_5). SDWA 1996 requires EPA to develop regulations that require disinfection of ground water systems "as necessary" to protect the public health. The Ground Water rule is scheduled to be promulgated in November 2000. Mr. Burneson noted the preliminary nature of the proposal sent to the DWC for review and that it might change after its review by OMB is completed. He discussed the development process for the rule which included agency workgroup interaction, stakeholder discussions, SBREFA consultations (small business), and circulation of a draft rule preamble in February 1999. He noted the CDC outbreak data on ground water systems from 1971-1996, occurrence studies in ground water systems that showed contamination in from 4 to 31 per cent of the wells (depending on the analytical routine used – cell culture vs. polymerase chain reaction tests), and the distribution of systems in the U.S.

Ground Water Regulatory Provisions under consideration include: 1) efforts to target ground water systems that are contaminated or may be at particularly high risk of fecal contamination (i.e., sanitary surveys, hydrogeologic sensitivity assessments, and source water monitoring) and 2) actions intended to ensure that contaminated systems and systems at risk take the steps needed to ensure safe drinking water (i.e., corrective action, and compliance monitoring). Flexibility is built into the provisions to allow states and systems to select the most effective method for finding and addressing contamination.

The Charge presented to the DWC asks the Committee to evaluate the premise that "...more than one fecal indicator may increase the likelihood of detecting fecal contamination than a single indicator" in two areas: 1) Based upon the available data, can each of the four candidate indicators (*E. coli,* enterococci, somatic coliphage, male-specific coliphage) be justified as a monitoring tool for determining the presence of fecal contamination in ground water? and 2) given the available data upon incidence, fate and transport of virus and bacteria through the soil/aquifer matrix, is it appropriate to monitor for both bacterial and viral indicators to determine the presence of fecal contamination?

12:20 - 12:35 pm **Public Comment:**

a) American Water Works Association: Dr. Alan Roberson, Director of Regulatory Affairs, American Water Works Association, noted again his concerns with the short time associated with the emergency FR notice and asked for additional time to submit written

comments (time is granted by the FR notice – until March 29, 2000). Dr. Roberson noted the complexity of the rule's provisions and the attendant difficulty his association predicts for State and utility understanding of and compliance with the rule. Many potentially impacted systems exist and it is essential to make sure we identify the correct ones to be addressed. He noted that the requirement could drive utilities toward disinfection regardless of the actual risk (see Attachment H).

b) Environmental Health Laboratories: Dr. Fu-Chih Hsu discussed the etiology of ground water related disease outbreaks and a monitoring study conducted to determine movement of coliphage and spores of *Bacillus subtilis*. The study demonstrated the detection of male-specific coliphage as early as day 2 after spiking and as late as day 45. He concluded that negative tests for total coliform and *E. coli* may not indicate that ground water is free of viral pathogens. Coliphage tests can be used to assess the vulnerability of ground water to enteric viruses and they are relatively simple, rapid, inexpensive, and reliable. He supported the use of coliphage and *E. coli* monitoring in ground water. Both somatic and male-specific coliphage should be used. Dr. Hsu also presented 12 letters from microbial scientists that support his position (see Attachment I).

11:20 - 12:20 pm The DWC and EPA Representatives.

The members discussed the technical background of the draft proposal with EPA representatives. The discussion focused on the Agency charge. The Lead Discussant was Dr. Moe. Associate Discussants were Drs. Toranzos and De Leon. Major messages from the committee members in response to Charge Question 2 focused on the following: 1) the DWC's support for monitoring for both bacteria and virus in both routine and "trigger" monitoring (supported by studies cited in the proposal, alone none of the tests is as capable as a combination of bacterial and viral tests, outbreak data supports a concern for viral diseases). In regard to Charge Question 1, the members noted that: 1) there is no strong rationale for picking *E. coli* over enterococci or the reverse; 2) one might logically lean toward *E. coli* because of the familiarity of the drinking water community with the procedures that are used to test for its presence; 3) a combined test for male specific and somatic coliphage should be preferred because it is easy to accomplish and each one detects a different population; and 4) the combined protocol for male specific and somatic coliphage may need to be validated.

In addition, the Committee discussed concerns with the possibility that some sites that will not need to treat will also not need to monitor. The combination does not seem to be sound when you consider that from 4-31 percent of sites could be contaminated. This level of contamination was greater than expected by scientists. The Committee suggested that an aggressive wellhead protection program combined with a source water assessment program would resolve the problem. In fact, such a program might be justification for decreased monitoring under this rule because of the monitoring and other practices that occur in that program.

The Committee was concerned that hydrogeological assessment on the basis of map

data would be inadequate to determine if aquifer contamination exists. Examples of supposedly confined aquifers being contaminated were noted by the Committee. Actual monitoring may be required instead of such assessments. Avoidance of a monitoring requirements should be made difficult. The Committee also noted a concern that transient non-community systems may cause many low level illnesses which go undetected (see discussion below in these minutes on Tuesday, 3/14/2000, from 8:00 am until 10:00 am for additional information).

12:15 - 1:15 pm **LUNCH**

5. Drafting Session

1:15 - 4:00 pm Break-Out Sessions to Draft DWC Comments on the draft Ground Water Proposal and the draft LT1/Filter Backwash proposal.

Two break out sessions were held to prepare initial draft reports that capture the Committee's comments made during the discussions on the draft proposals for the LT1/Filter Backwash (Room 6013) and Ground Water rules (room 6530). These sessions generated electronic files of the draft reports for these topics. Drafts prepared during the sessions were distributed to Committee members and the public in attendance at the meeting for familiarization prior to day two's consensus and agency debrief sessions. A number of committee members also gathered together to informally discuss the background materials provided on arsenic that was a subject of a briefing later in the day. Members from the public joined this group as well.

During the breakout sessions, the DFO was contacted by a television news bureau representative who noted a camera crew would be sent to prepare some background tape of the afternoon session. The intent was to use the visuals in reporting on an environmental coalition's release of a report on their analysis of EPA's experience with the drinking water right to know provisions of SDWA. The cameraman taped for less than five minutes and departed.

6. Planning Session for the Remaining FY 2000 DWC Calendar

This series of interactions included briefings by EPA representatives on a number of ongoing activities relevant to drinking water research and regulation. The interactions identified the nature of the Agency activities underway and the status of those activities. The intent was to identify issues of importance in the upcoming SAB - EPA interactions on each topic (likely charge, issues, controversial items, etc.). Firm commitments for review of two of the issues were developed.

4:15 - 4:45 pm **Candidate Contaminant List (CCL) Research Strategy Briefing**
Dr. Robert Clark, ORD and DWC Members

Dr. Clark discussed the progress made in developing the research strategy for CCL Number 1 as well as the desired timing and focus of the review that will be requested of the DWC later in FY 2000 (see Attachment J). Dr. Clark noted that SDWA requires EPA to

establish a list of unregulated microbiological and chemical contaminants to aid in setting priorities for its drinking water program. CCL Number 1 was published during 1998 and it contained some 60 contaminants that EPA needs to determine whether to regulate. EPA has decided that there are sufficient data to make such a determination by the August 2001 statutory deadline for 20 of the 60 listed contaminants ("Regulatory Determination Priorities"). Of the remaining contaminants some have been identified as "Research Priorities" and others as priorities for "Occurrence Data Collection." These will be included in CCL Number 2 that must be published during 2003. They are also the primary focus of the research strategy being developed.

Dr. Clark noted that CCL research priorities were discussed in a September 27-29, 1999 workshop with participants from EPA, other agencies, consultants, academia, and water utility representatives. At the workshop, four workgroups considered research needs for the CCL. These included groups for: 1) Chemical Health Effects, 2) Chemical Methods & Exposures, 3) Microbial Health Effects, Methods & Exposures, and 4) Treatment (microbial and chemical). Examples of the output from each were presented. A report of the workshop is now being drafted.

Dr. Clark presented a schedule for the Research Strategy that included the following items:

1) CCL Research Strategy was first drafted (August 1999)
2) Stakeholders Workshop (September 1999) (summary is now being drafted0
3) Revised Strategy (April, 2000)
4) ORD Science Council Review (May, 2000)
5) EPA SAB Review (July was suggested but the DWC is not available for the review until August 8-9, 2000)
6) EPA Final Strategy (September 2000)

Dr. Bull noted that the EPA SAB Research Strategies Advisory Committee identified CCL research as a priority area. It should be viewed in relation to the information in the framework just discussed. In addition, the Committee questioned why the research budget at EPA is flat in the face of rising federal research budgets elsewhere. Dr. Clark suggested that the Agency is expected to work with these other agencies to leverage their research efforts in a manner that will permit some of their work to also consider environmental dimensions to the problems being addressed.

The DWC members decided to meet on August 8-9, 2000 to conduct its review of the Agency's CCL Research Strategy.

4:45 - 5:20 pm **Non-Radon Radionuclides Briefing**
Mr. William Labiosa, David Huber, and James Taft

James Taft discussed the disposition of the **Radon** rulemaking during this interaction (See Attachment K_1–EPA overheads; K_2–SAB Commentary on Radon; and K_3–American Water

Works Service Company, Inc. written comments). The proposal provides flexibility for meeting an MCL of 300 pCi/L in drinking water or an Alternative MCL of 4,000 pCi/L in drinking water if a multimedia mitigation program (MMM) is established to address indoor air exposure to radon. The proposal was published on November 2, 1999 and comments closed on February 4, 2000. A final rule is due in August 2000. An SAB briefing was conducted after the proposal was published and an Executive Committee Commentary was sent to EPA on January 13, 2000. That commentary deferred to the numerous past SAB radon reviews and noted the need for additional time to respond to future drinking water rule making proposals. A review now being completed by the SAB's Environmental Economics Advisory Committee is also relevant to this rulemaking.

The agency discussed the actions associated with their NRR Notice of Data Availability (NODA) that will be released in April, 2000. Dr. Janet Johnson, Chair of the EPA SAB Radiation Advisory Committee, participated in the discussion by telephone connection (See Attachment L_1–EPA overheads on Revising the Current Rule and L_2–EPA overheads on the NODA).

Historically, a 1976 National Interim Primary Drinking Water Rule established an MCL for Radium 226 and Radium 228 at 5 pCi/L; a Beta/Photon emitters MCL of 4 mrem/year, and an Alpha emitters MCL of 15 pCi/L excluding uranium and radon.

The 1986 SDWA reauthorization finalized all NIPDWRs with MCLs being set by law for combined radium, gross Alpha and Beta particle and photon radioactivity from man-made radionuclides. The reauthorization also required EPA to promulgate MCLGs for currently regulated radionuclides and to propose/promulgate a regulation for uranium.

The 1996 SDWA reauthorization required EPA to remove radon from the proposal. It also stated that MCLs must maintain or provide greater protection to health of persons and that MCLs may be set a levels higher than "feasible" if the Administrator determines that the benefits do not justify the costs at the feasible level. A court agreement with the Bull Run Coalition provides a November 21, 2000 date for final promulgation.

The 1991 proposal and the 2000 NODA were compared by EPA. Details are in Attachment L_1. The NODA will provide new health data and risk analysis for existing regulations and uranium, new cost and benefits analysis for monitoring of Radium 228 and the final uranium regulation. The NODA requests data, comments on interpretations, and input for completing the uranium regulation and for acting on the proposal to include NTNCWSs. The presentation included information on the Health Effects changes since 1991.

The schedule for the rulemaking is as follows:

1) NODA to be published in the Federal Register within two to three weeks (by calculation that would be from March 27 to April 3).

2) Sixty day comment period to end in late May or early June

3) Final Agency review in June and July

4) OMB review August - October

5) Final rule published in the FR in November 2000

The Agency also discussed their analysis of costs and benefits associated with the proposal as modified by the NODA. Benefits are based on EPA Office of Radiation and Indoor Air's risk factors, an assumption of 1.1 L/day average consumption, and using valuation techniques used in recent rules that are based on reductions in fatal cancer cases. Issues involved in the calculation of benefits include latency, cancer, premiums, etc and are discussed similarly to the manner in which they were discussed in the Radon proposal. Cost models are based on national costing models for radon and use standard model systems assumptions from the Drinking Water Baseline Handbook. The compliance decision tree assumes most non-compliant systems will treat and that most ground water systems that treat will use ion exchange softening, other water softening, or green-sand/oxidation filtration. Compliance of remaining systems assumes that they will purche water, develop new wells, or blend (see Attachment L_2).

Mr. James Laity, Office of Management and Budget, noted that procedurally, this committee would not be asked to further review this rulemaking. The NODA will elicit some public comment and a final promulgation will occur in November, but the envisioned process does not include a proposal stage and therefore no additional review is to be requested.

Drs. Bull and Johnson noted that they would obtain the NODA as soon as available, consider its provisions, and then poll members of the DWC and the SAB Radiation Advisory Committee to determine if there is interest in hearing more of the details from the Office of Water at the April RAC meeting. Any SAB commentary would be decided upon at that time by the RAC.

5:50 pm The meeting was adjourned for day one.

Tuesday, March 14, 2000

8:00 am **Reconvene the Meeting**

8:00 - 9:00 am **Committee Review and Consensus on Draft Documents**

8:00 - 8:20 am Review and Approval of DWC Report on LT1/Filter Backwash Proposal

Dr. Trussell led the Committee in its discussion of the major points contained in the draft developed in Monday's breakout session on this proposal. Major points agreed to are

contained in Attachment M to these notes. The members agreed on the draft given that the noted changes are made. Tom Miller will reformat the report and distribute it to the DWC members for approval during the week of March 27, 2000. The intention is to have the report reviewed by the SAB Executive Committee during an April telephone conference meeting if timing is consistent with SAB practice. Otherwise approval will be sought at a May conference meeting.

8:20 - 9:00 am Review and Approval of DWC Report on Ground Water Proposal

Dr. Moe led the Committee in its discussion of the major points contained in the draft developed in Monday's breakout session on this proposal (see Attachment N to these minutes). Dr. Moe discussed the specific comments that respond to Charge Questions 1 and 2 from EPA. The members agreed to the statements on the draft in regard to the two charge questions contingent upon the noted editorial changes being made. Dr. Moe will revise the draft and send it to Tom Miller by March 24, 2000. Mr. Miller will reformat the report and distribute it to the DWC members for approval during the week of March 27, 2000. The intention is to have the report reviewed by the SAB Executive Committee during an April telephone conference meeting if timing is consistent with SAB practice. Otherwise approval will be sought at a May conference meeting.

In addition to the direct responses to the charge questions, Dr. Moe noted that it would be good to consider whether the DWC should address some miscellaneous issues that were raised by EPA as questions in the draft proposal. These issues will be discussed by a workgroup consisting of Drs. Moe, Toranzos, and De Leon and they will deliver a recommendation to the full Committee on whether they should be further pursued. If they so recommend, the DFO will schedule a public DWC telephone conference meeting as soon as possible to allow the committee to discuss the issues and to agree on points to include in a subsequent report to EPA.

One general issue was raised by members during the discussion. This was the problem presented to reviewers who are considering a regulatory package which refers to, but does not include, detailed technical information on the science that supports the rulemaking. This occurred for the ground water rule in the area of monitoring technologies that were cited in the package; however, technical information on the issue (that is, the actual technical papers) was not provided and the members could not thoroughly analyze the accuracy of the statements made about the methods. Committee members noted that for future reviews, it will be important to identify and provide the relevant technical support documents that underpin Agency proposals.

9:00 - 10:00 am **Debrief for the agency on the DWC comments.**

9:00 - 9:30 am Debrief on the DWC Comments on EPA's Draft LT1/Filter Backwash Proposal

Dr. Trussell led the Committee's debrief for the Agency on the draft proposal. The debrief focused on the major points contained in the draft comments agreed to in the previous session of this meeting. Major points noted for the Agency are contained in Attachment M to these notes.

Mr. James Laity, OMB, asked if any of the committees concerns with recycle points were addressed by State and water system consultations that allow them to work out the point where recycling is best. The committee noted that their statement still stands. There is a need to be clear on the issue. If the consultation identifies the correct point to recycle, its fine; but if it does not get it right then there is a problem. The issue is that the "ahead of" term does not always get you to the right point. The committee did note that the idea of a consultation was valuable.

9:30 -10:00 am Debrief on the DWC Comments on EPA's Draft Ground Water Proposal

Dr. Moe led the Committee's debrief for the Agency on the draft proposal. The debrief focused on the major points contained in the draft comments agreed to in the previous session of this meeting. Major points noted for the Agency are contained in Attachment N to these notes.

The Committee discussed the idea of using a combined protocol to detect both male specific and somatic coliphage. Because a combined protocol would not be a major departure from the approach used in conducting separate tests for each coliphage, the extent of a round robin validation needed for a combined host protocol was thought to be less burdensome. The committee reinforced its concern for the potential for systems that do not treat to also be excused from a monitoring requirement. Frequency of such monitoring will need to consider the cost of doing so. In response to a question from EPA, the Committee did agree that using the same bacterial method across the board would provide the opportunity for comparing results obtained in different locations.

10:00 - 10:15 am **Break**

7. Planning Session Continued - Arsenic Proposal
Irene Dooley, James Taft, and Rita Schoeny

10:15 - 11:45 am Interaction on Arsenic

The intent of this briefing and discussion was to plan for the Committee's formal review of the Agency proposal (see Attachments O_1 and O_2). Mr. James Taft introduced the topic by discussing the history of arsenic regulation which goes back to 1943 at which time the PHS published a 50 microgram per Liter level. The same level was established by the 1975 IDPDWR and the 1985 proposed NPDWR.

Agency review continued over the intervening years until the 1996 reauthorization of SDWA in which a regulatory deadline was established. SDWA 1996 required a research plan to reduce the uncertainty in assessing health risks from low levels of arsenic (February 1997), the

conduct of research in consultation with the NAS, Federal agencies, and interested public and private entities, proposal of an MCL, MCLG, and compliance technologies by January 1, 2000 with final promulgation by January 1, 2001. The proposal date has been missed, but EPA intends to promulgate by the January 1, 2001 deadline. Other requirements in the act require the use of the best available peer reviewed science and the specification of a methodology to reconcile inconsistencies in the data, the conduct and publication of a Health Risk Reduction and Cost Analysis (HRRCA) of each alternative considered, assessing co-occurrence, cost of other regulations, and health effects of populations at greater risk. The Agency may issue an MCL that maximizes health benefits at a cost justified by the benefits. The MCL is to be reviewed at least every 6 years.

Dr. Rita Schoeny discussed the NRC report on arsenic. The NRC charge asked for:

1) a review of EPA's characterization of human health risk (ingestion of Arsenic forms in food and water; identify uncertainty in the characterization);
2) a review of quantitative and qualitative evidence of cancer and non-cancer health effects and its relevance to risk from arsenic in drinking water;
3) a review of data on toxicokinetics, metabolism, mode of action – for risk assessment;
4) priorities for research;
5) consideration of the current MCL of 50 micrograms/Liter under SDWA and the Clean Water Act criterion of 0.018 micrograms/Liter.

The NRC report was issued on March 23, 1999. It concluded that:

1) With respect to Health Effects:
   a) Sufficient evidence from studies in Taiwan, Chile, and Argentina that ingested arsenic (at hundreds of microgram/Liter) causes bladder, lung, and skin cancer;
   b) Noncancer effects include gastrointestinal, hematological, neurological, dermal, peripheral vascular, cardiovascular, diabetes, and immune system effects;
   c) No demonstration of developmental or reproductive effects, but that arsenic crosses the placenta;
   d) No demonstration of essentiality in humans

2) With respect to Mode of Action-Cancer:
   a) Arsenic induces chromosomal changes without direct DNA interaction (no point mutations);
   b) Arsenic induces cell proliferation and it can be a co-mutagen (affects DNA methylation);
   c) Arsenic-induced effects on cellular housekeeping processes are more likely to result ultimately in chromosomal alterations

3) With respect to Mode of Action-Dose Response:

a) MOA considered to be most plausible lead to dose-response curve that is sub-linear in the low dose range;
b) But, current evidence does not meet EPA's 1996 criteria for departure from default of linearity (can't determine the shape of the curve at low doses);
c) And, perturbations in cellular function related to plausible MOA might be operating at arsenic exposures associated with the current MCL.

4) Statistical Considerations:
a) NRC cautions on using ecological data and broad exposure categories;
b) Bladder cancer data have advantages over skin (age breakdown more reliable, arsenic available for each of 42 villages);
c) Model choice has impact; Poisson regression is more stable than multistage Weibull;
d) POD, 1 percent excess risk is about 400 ppb; MOE of 8 from the current 50 microgram/Liter MCL.

5) Risk considerations:
a) EPA should analyze bladder, lung and other internal cancers independently and calculate cancer endpoint;
b) Using POD of 400 ppb, risk of bladder cancer at the current MCL is estimated at 1 to 1.5 per 1,000;
c) Excess lung cancer deaths from arsenic may be 2 to 5 times higher than bladder cancer deaths;
d) Risks calculated for Chile and Argentina populations are comparable

6) General Conclusion of the NRC:
"On the basis of its review of epidemiological findings, experimental data on the mode of action of arsenic, and available information on the variations in human susceptibility, it is the subcommittee's consensus that the current EPA MCL for arsenic in drinking water of 50 Fg/L does not achieve EPA's goal for public-health protection and, therefore, requires downward revision as promptly as possible."

Dr. Schoeny also presented the draft charge that the Agency would like the SAB Drinking Water Committee to consider in its arsenic review. The charge includes the following elements:

1) Based on SAB's review of the health effects in the preamble of the proposed rule, are there any important issues from the NRC report and conclusions not adequately identified or considered by EPA? For example:
a) Concentration of inorganic arsenic as principal form causing health effects;
b) Implications of mode of action (characterization of dose response given EPA's 1996 draft Carcinogen Risk Assessment Guidelines and

overestimation of risk discussion);
c) Implications of natural arsenic exposure through food.

2) Does SAB have advice on evaluation of multiple endpoints of arsenic in drinking water, both quantified and not-yet-quantified (bladder, lung, cardiovascular, skin, other)?

Ms. Irene Dooley discussed additional risk management considerations with the Committee. These included:

1) Arsenic occurrence;
2) Practical Quantitation Limits (3 Fg/L)
3) Arsenic treatment
4) Benefits

The next steps for arsenic decision making include OMB review (from mid-February to mid-May) and an early June proposal in the Federal Register.

11:45 - 11:55 am **Public Comment:**

a) American Water Works Association, Dr. Alan Roberson discussed uncertainties in the Taiwanese study and called for additional studies of actual arsenic exposure in the U.S. In addition he noted uncertainties that exist in analytical methods for arsenic, costs associated with handling waste residuals resulting from treatment, affordability, and appropriate ways to estimate the benefits that might result from reduced cancer mortality from arsenic control (see Attachment P). Dr. Roberson also provided articles on costs of arsenic control, determining a PQL for arsenic, and a report prepared for AWWA by Stratus Consulting, Inc. entitled *Entry Points to the Distribution System in Ground Water Community Water Systems* (see Attachments Q_1, Q_2, and Q_3).

11:55 - 12:05 pm

b) Arsenic Research Council, Dr. David Cragin stated that a drinking water standard will cross over and affect actions taken in waste management areas (see Attachment R). He questioned the appropriateness of a zero MCLG, suggested the existence of inconsistencies in the NAS report and disagreements with the conclusions by some who served on the panel (Agency representatives countered the assertion of panel internal dissension by mentioning a letter to EPA noting that all Panel members agree with and endorse the report and state that reports of conflict are taken out of context), and that common sense and observation suggest that arsenic related health problems do not occur in the U.S.

12:05 - 12:40 pm The DWC completed its discussion with the Agency

Issues mentioned by the DWC included: 1) the possibility of doing an MOE analysis along with a linear extrapolation of cancer risk; 2) the possibility of looking at all risks instead of just a marginal cancer risk; and 3) whether the need to categorize carcinogens leads one to the conclusion to use linear estimation techniques.

The panel also considered the charge and suggested the need to consider engineering and cost issues, additional expertise to include on the Arsenic Review Panel (NRC panelist, economist, additional toxicologists), and the schedule for the review. The DWC members decided to meet and conduct the review on June 5, 6, 7, 2000.

Mr. Laity of OMB suggested that the meeting did not need to wait for final completion of the OMB review and revision of the proposal before going forward. He noted that a number of analyses are now available that could be provided to the DWC as technical input for the proposed rule. Documents that might be of use to the Committee include: the NRC report, the HRRCA, a decision tree, the proposed rule itself, the health effects portion of the preamble. Others useful documents will be considered as the review is further planned.

12:40 - 1:30 pm **LUNCH**

8. Microbial/Disinfection Byproducts 2: Stakeholder Process and Possible Actions/ Issues for DWC-EPA Interaction (1:30 - 2:30 pm)

Mr. Ephraim King discussed Agency actions and possible interactions with the DWC as a result of the proposals to be developed from the Stakeholder process. Elements discussed by Mr. King are included in the left side of the following Tables. The right side suggests some possible places where an EPA - SAB/DWC interaction could be important.

1) M/DBP Stage 2 Decision Support Activities

M/DBP ELEMENT	POSSIBLE DWC ACTIVITY

1. Goal is to balance chemical and microbial risk considerations in the decision-making process	
2. Data Analysis (ICR treatment and occurrence, small systems, cost, toxicology and epidemiology relative to reproductive and developmental effects).	2. Assistance in determining the bottom line for health risk given the data available.
3. Regulatory Development Process (stakeholder interactions on the available data and the development of problem statements and solutions).	
4. Schedule (agreement in principle 7/2000; stage 2 proposal 3/2001; promulgation 5/2002)	
5. DBP Risks - Cancer (no substantial new data since 12/98 to go beyond stage 1)	4. Regardless of the interactions desired, there is ample time for EPA and the Committee to work together to engage on the science issues.
6. DBP Risks - Reproductive/Developmental effects (acute exposure concerns exist).	6. Possible topic for DWC interaction.

M/DBP Stage 2 Decision Support Activities (Continued)

M/DBP ELEMENT	**POSSIBLE DWC ACTIVITY**

7. DBP Risks - Unknown/Uncharacterized DBPs (How to consider the risks in combination or use surrogates? How to deal with incremental impacts without disruption to the industry). 8. Stage 1 Baseline Projections (where will the industry be as a result of compliance with stage 1 and what that means for stage 2). 9. TTHM occurrence data from ICR vs. Stage 1 projections. 10. Potential Stage 2 DBP approaches being considered include: lower MCLs, MCLs for individual DBPs, MCLs for currently unregulated DBPs, monitoring based on maximum concentrations not average.	9. Implications of the compliance projections 10. Review risk assessments for reproductive/ developmental effects, review benefits assessments, evaluate treatment effectiveness for control of DBPs that are not measurable and for which a Treatment Technology is required instead of an MCL

SAB members asked what commitment EPA and Stakeholders had with respect to the FACA process now underway for M/DBP2. Mr. King noted that EPA had committed to proposing a rule that is consistent with the agreement in principle for issues so addressed. For unaddressed issues, EPA will propose elements developed in a reasonable manner in lite of the agreement. However, it is not legally possible to make that firm a commitment for final promulgation. He also noted that EPA is a full stakeholder member in those proceedings as contrasted to only a recipient of advice in other FACA processes. The Committee noted that the FACA process does not seem to be leading to a clear bottom line for health issues. There is relatively strong information for cancer, but for reproductive/ developmental effects, the state-of-the-art is about where cancer was for stage 1.

The DWC decided to not become involved in the M/DBP 2 process until after the stakeholders reach their agreement. SAB involvement will be more credible at that point. Dr. Moe noted that a major epidemiology study focused on reproductive/developmental effects is now underway at CDC with AWWARF funding. In 5 years, we should have a better idea of those risks.

2) Long-Term 2 Enhanced Surface Water Treatment Rule Decision Support Activities

LT2ESWTR ELEMENT	POSSIBLE DWC ACTIVITY
1. LT2 is needed to incorporate occurrence data not available for LT1, to ensure microbial protection concurrent with DBP Stage 2 actions, and to do more on *Cryptosporidium*.	
2. *Cryptosporidium* occurs in most source waters; additional strains are being identified each having a different infectivity rate and distribution; uncertainty exists regarding other strains not yet identified.	2. Relationship between occurrence and infectivity.
3. ICR data suggests that a small subset of systems have a higher *Cryptosporidium* level.	3. Assist in determining why some systems have higher oocyst levels than others.
4. EPA assumes that filtered systems achieve >2 log removal of *Cryptosporidium* (some as high as 5) but unfiltered systems present no treatment barriers to the organism.	4. Consider the need for an inactivation requirement for LT2. Which systems should be the focus?
5. What should be done about distribution systems (cross connection control, uncovered reservoirs, other)?	

The Committee congratulated EPA for including an emphasis on drinking water distribution systems in the future. It is clear that systems can provide clean water at the plant exit, but what happens in the distribution system is uncertain.

2:55 pm **The meeting was adjourned**

I certify that these minutes are accurate to the best of my knowledge.

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Dr. Richard J. Bull
Chairman
Drinking Water Committee

Mr. Thomas O. Miller
Designated Federal Officer
Drinking Water Committee

Attachments:

A Federal Register, 65(39), Monday, February 28, 2000. Pp10493-10494
B Agenda
C Committee Roster
D Sign-in Sheets
E_1 Overheads; LT1ESWTFBR
E_2 Fact Sheet; LT1ESWTFBR
E_3 Draft Proposal: Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Rule (EPA document under development)
F Public Comments; American Water Works Association-LT1ESWTFBR
G_1 Overheads; Ground Water Rule
G_2 Charge to the SAB; Ground Water Rule
G_3 Background Information on Fecal Indicator Monitoring for Ground Water Sources
G_4 Fact Sheet; Ground Water Rule
G_5 Draft Proposal: Ground Water Rule (EPA document under development)
H Public Comments; American Water Works Association-Ground Water
I Public Comments; Environmental Health Laboratories- Ground Water
J Overheads; Status of the CCL Research Strategy
K_1 Overheads; Radon in Drinking Water
K_2 SAB Commentary on the Agency's Proposed Drinking Water Standard for Radon
K_3 Public Comments; (written only) American Water Works Service Company, Inc.-Radon
L_1 Overheads; Radionuclides: Notice of Data Availability
L_2 Overheads; Finalization of the 1991 Radionuclides Proposal-NODA
M SAB Draft Comments on Long Term 1/Filter Backwash Proposal
N SAB Draft Comments on Ground Water Proposal
O_1 Overheads; Arsenic in Drinking Water, Regulation Overview
O_2 Health Effects Excerpt from the Draft Arsenic Proposal (EPA document under development)
P Public Comments; American Water Works Association-Arsenic
Q_1 Public Comments; AWWA "Cost to utilities of a lower MCL for Arsenic"
Q_2 Public Comments; AWWA "Determining the practical quantitation level for arsenic."
Q_3 Public Comments; AWWA "Entry Points to the Distribution System in Ground Water Community Water Systems"
R Public Comments; David Cragin (Arsenic Research Council)
S Overheads; Stage 2 DBP Rule & LT2ESWT Rule